MED SYSTEMS®

Electro Flo® 5000
Airway Clearance System

User Manual

www.medsystems.com

Rx only

Patents Pending Made in U.S.

P/N 5011, V/11/12/13

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Read this guide completely before using your Electro Flo® 5000 System

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Federal law restricts this device to be sold by or on the order of a physician or on the order of a licensed practitioner.

Definitions

This manual contains words and symbols that bring attention to specific statements.

WARNING – Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION – Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury, or failure or damage of the device.

How does the Electro Flo 5000 work?

Percussion has long been held as the best method for loosening trapped mucus within the lungs. Historically, the first and still the most effective percussion method used for respiratory therapy is the rhythmic striking with human hands on the chest wall. The MED SYSTEMS® Electro Flo 5000 with Force-Multiplying Technology tirelessly mimics hand percussion without user fatigue.

Airway Clearance Therapy (ACT) loosens thick, sticky mucus so that it may be cleared by huffing and coughing. Gravity helps to ensure effective outcomes, so use postural drainage positions to aid in moving mucus from the lungs up to the throat.

The Electro Flo 5000

- Is designed for convenient, personalized Chest Physiotherapy (CPT)
- May be self-administered over individual lobes
- Is automated, consistent, true percussion, not massage
- Precisely controls power and frequency of percussion separately
- Varies from light tapping to major impact
- Delivers deep, pulse percussion
- Is light weight, compact and portable
- Will quickly and easily help increase sputum mobilization

Indications for Use

The Electro Flo 5000 is intended to assist in airway clearance therapy when the physician's choice of therapy is external manipulation of the thorax. Additionally, the Electro Flo® 5000 is indicated for external manipulation of the thorax to promote airway clearance and improve bronchial drainage.

Contraindications

- The Electro Flo 5000 is not intended for infants or children less than 50 lbs.
- The Electro Flo 5000 should not be used on patients who have severe calcium deficiencies or severe osteoporosis.

CAUTION – The Electro Flo 5000 should not be used on patients who:

- Have just eaten or are vomiting
- Have acute asthma or tuberculosis
- Have brittle bones, broken ribs or severe osteoporosis
- Are bleeding from the lungs or coughing up blood
- Are experiencing intense pain
- Have increased pressure in the skull
- Have head or neck injuries
- Have collapsed lungs or a damaged chest wall
- Have recently experienced a heart attack
- Have a pulmonary embolism or lung abscess
- Have an active hemorrhage
- Have injuries to the spine
- Have open wounds or burns
- Have had recent surgery

Safety Instructions

WARNING – To reduce the risk of electrocution, fire, or personal injury, follow these instructions:

- Keep this device out of the reach of children.
- Do not use the Electro Flo 5000 with or in water.
- Do not use near flammable anesthetics or near fire.

CAUTION

- Electro Flo® 5000 is a prescription restricted device, intended for the person for whom it was ordered and only for the use for which it was intended.
- Never immerse the unit in any liquid.
- Product is to be used only as described in this manual and only as prescribed by a physician.
- Inspect power cord and unit prior to use. Do not use this product if any damage has occurred to power cord or any part of the system.
- Do NOT insert any object into any opening on the system.
- Always observe ALL warnings, cautions, and notes listed in this manual.

Electro Flo® 5000 System Description

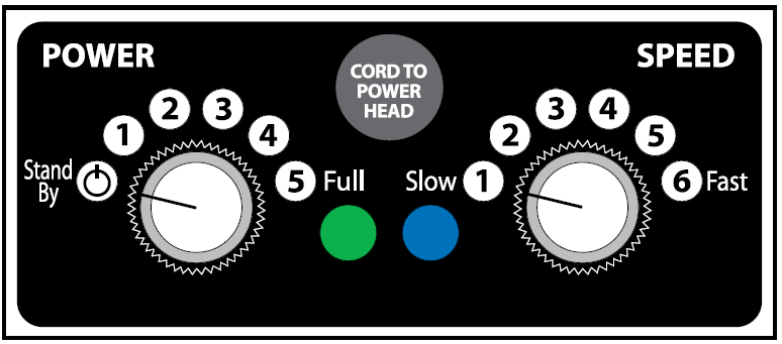
The Electro Flo® 5000 System is composed of the following assemblies:

- Control Box
- Power Head
- Self-Administrator® Strap
- Carrying Case
- Operator Manual

The power and speed of the percussor may be increased by turning the knobs clockwise. There are 5 power settings and 6 speed controls, making 30 combinations available for individual percussive needs.

Electro Flo® 5000 – Control Box and Power Head

There is a 10 foot power cord to connect the Control Box to an outlet and a 6 foot cord between the Control Box and the Power Head.



Electro Flo® 5000 – Control Panel

Green Light = POWER ON • Blue Light = SPEED RATE

The power switch is located on the back of the unit on the lower right side.

ON and OFF Switch

Self-Administrator® - Personalized CPT

The Self-Administrator® is a strap that holds the Electro Flo® 5000 Power Head to allow a patient to CPT directly on their back, unassisted, and precisely where needed for immediate relief.

The Self-Administrator

The Self-Administrator can be used by anyone with manual dexterity. It has adjustable straps that can be adjusted to fit anyone's reach and for the treatment position being used.

Adjustable Straps

Refer to MED SYSTEMS website for a demonstrational video of percussion treatment with the Self-Administrator.

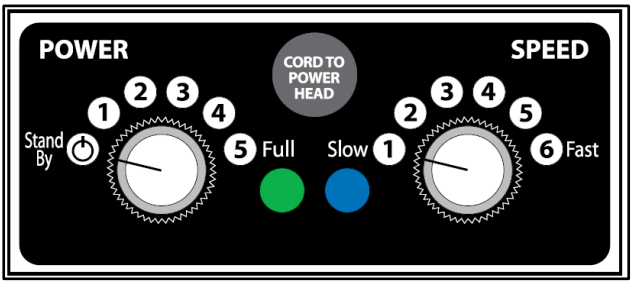
Operating Instructions

Step 1 – Setup

a) Begin by gathering all necessary materials such as tissues, pillows, and towels.

b) Remove equipment from carrying case and set-up on a stable horizontal surface.

c) Before plugging the unit in, fully turn both knobs counter clockwise on the Control Panel.



d) Plug the unit DIRECTLY into a properly grounded three-pronged 120 volt electrical outlet.

Self-Administrator Strap Setup

e) When using the Self-Administrator Strap, place it on a flat surface with the opening toward you and the Med Systems logo away from you.

f) Open the Velcro closure and insert the Electro Flo 5000 Power Head as shown. **Placing the bottom of the Power Head in first will help with insertion. It will be a snug fit.**

g) Tighten the Velcro closure securely.

CAUTION – The cooling fan must be running to ensure successful cooling of the percussor Power Head. If the cooling fan is not operating, unplug and contact MED SYSTEMS for repair.

Step 2 – Treatment

CAUTION

- Do not percuss over bare skin.
- Do not percuss directly on the shoulder blade, collar bone, spine, breast bone (sternum) or breasts.
- Do not place Self-Administrator over head or around neck.

a) At this time, the patient may assume a postural drainage position. Techniques and settings may vary with each treatment.

Follow Postural Drainage Therapy guidelines as directed by your physician.

b) **Turn on Unit** - Press the upper part of the switch on the back of the Control Box to turn the unit ON. The green indicator light will come on the Control Panel, showing power is on and the fan is running. The unit may cycle once. This is normal.

c) The blue indicator light for speed will be OFF and there will be no percussive action.

d) Start at the lowest settings of power and speed as shown by the lines on the knobs.

e) To achieve percussive action, turn the power knob one step from Stand By to 1. This will begin low power, slow speed percussive action. The blue light will blink at the speed rate of percussion.

f) Adjust the Electro Flo 5000 Control Panel's power and speed settings to desired positions.

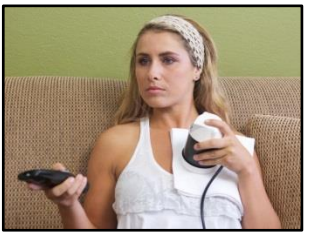
g) Pressing against area being treated while applying pressure to the top cover will multiply the applied force and intensify the treatment.

Electro Flo's Force Multiplying Technology is activated when pressure is applied onto the top of the Power Head cover.

CAUTION

- Percussion should not hurt. If it does, STOP. Reduce the pressure applied to the rear cover and /or reduce the power setting on the Control Box.
- Do not block the fan vent with your hand or fingers.

h) Treat each area to be drained for approximately 3 minutes.

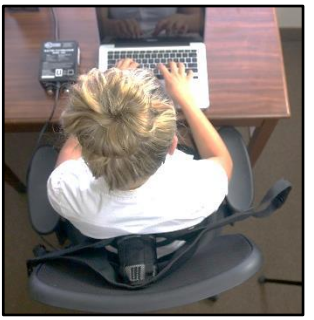


i) You may use the Self-Administrator to reach lobes on the back or front.

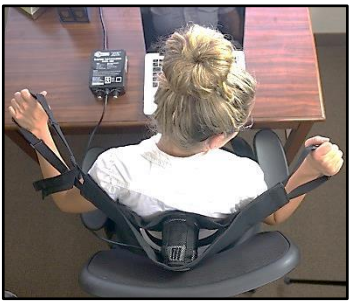
j) You can leave the Power Head in the Self-Administrator to easily apply to the front of the chest.

- **Take deep breaths throughout the treatment.**
- **Coughing is a normal result and a benefit of percussion.**
- **Limit percussion to 20 minutes maximum per session to avoid overheating the system.**

k) Positioning the Power Head firmly between your back and a desk chair allows for a hands free treatment.



NOTE – If the Power Head slips out of the Self-Administrator during treatment, pulling the straps toward the chest will correct its position.



CAUTION – Avoid using the unit in a dusty environment or laying the Power Head on a blanket as the lint from the blanket may be drawn in by the fan and damage the unit.

Step 3 – Shutdown

a) After use, turn the power knob counter clockwise to the Stand-by position. This will stop percussion and cycling power, but allow the unit to cool with the fan running.

b) If using the Self-Administrator, remove the Power Head from the strap and place it on a lint free surface for COOL DOWN.

CAUTION – Do not unplug or switch off the unit until COOL DOWN is complete.

c) To turn off the unit, press the lower half of the power switch. The GREEN LED will turn off and the fan will stop. Unplug the power cord from the outlet.

Cleaning Instructions

Control Box and Power Head

While system is turned off and unplugged, wipe the outside of the Power Head and Control Box using an isopropyl alcohol (IPA) wipe or a disinfecting wipe, as needed.

CAUTION - DO NOT spray disinfectant on the Control Box and Power Head; this can cause fluid ingress and damage the system.

CAUTION - DO NOT autoclave. DO NOT gas sterilize with ETO. DO NOT clean with aromatic hydrocarbons.

Self-Administrator

- To disinfect, use an alcohol pad or disinfectant wipe.
- Clean by wiping down with cool water and mild detergent or hand wash and allow to air dry out of direct sunlight.
- Clean Velcro area on straps using a comb or brush to remove any debris or dirty from the Velcro.

Carrying Case

- Clean by wiping down with a cool water and mild detergent or disinfectant wipe.
- Allow to air dry out of direct sunlight.

CAUTION – DO NOT use bleach on fabric.

Maintenance

1. The percussor cooling fan draws in 4 cubic feet per minute of air. Therefore considerable dust and lint can be drawn into the percussor filter.

   CAUTION – If the percussor filter becomes clogged with lint deposits, the unit will shut off permanently.

2. Inspect the percussion fan vent regularly. Use compressed canned air once a month, or as needed, to clean and remove lint from the fan located in the Power Head. Spray air onto the fan opening, following usage directions on the can.

CAUTION – Do not insert extension tube into the opening as is it might damage the fan.

Repairs

NOTE – The Electro Flo 5000 has no user-serviceable parts; contact MED SYSTEMS if it appears to be malfunctioning.

1. DO NOT DISASSEMBLE THE UNIT AT ANY TIME.

2. Any unit needing repair must be returned to MED SYSTEMS directly. **Return any unit, for repair, which does not:**
   - Cycle
   - Have a running fan
   - Show a green light while plugged in and the power is switch on
   - Show a blinking blue light when power is turned above the Stand By position
   - Have percussive action with a blinking blue light and running fan.

3. For any of the above criteria, please contact MED SYSTEM Customer Service for processing your return at the following numbers:

   U.S. Toll Free 800-345-9061

   Outside U.S. 858-483-9671

4. MED SYSTEMS will ship a loaner unit to you.

5. Carefully pack the percussor that you are returning in the box provided.

6. Product exchange instructions will be included with the loaner unit.

Warranty

Electro Flo 5000 & Self-Administrator – MED SYSTEMS warrants the products against defective materials or workmanship for three years from date of purchase.

MED SYSTEMS shall replace or repair any product deemed defective, upon receipt of written claim of defect, at its option. The user of this product shall have the sole responsibility for any malfunction which results from improper use.

Note – This warranty does not cover ordinary wear and tear arising from the normal use of the product. The user of this product shall have the sole responsibility for any malfunction which results from improper use.
The following conditions will cause the warranty to be null and void:

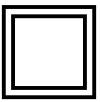
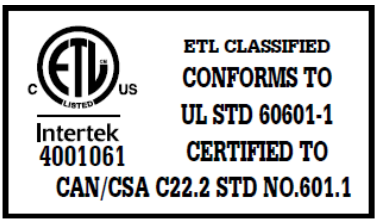
- Plugging the unit into an outlet that supplies more than 120 VAC
- Submersing the unit in water
- Operating the unit in an environment outside the specifications
- Disassembling the unit in any way
- Any maintenance performed outside the factory

The foregoing warranty is in lieu of all other warranties whether expressed or implied, including but not limited to, any warranty of merchantability of fitness for a particular purpose not existing in connection with sale or use of this product.

Operating Environment

Operating Temperature	50°F to 95°F (10°C to 35°C)
Storage & Transport Temperature	32°F to 158°F (0°C to 70°C)
Relative Humidity	MAX 95%, Non-Condensing

Specifications

Category	**Specification**
Product Type	Medical Chest Percussor Durable Medical Equipment
Model	Model 5000
Electrical Classification	Type BF, Patient Contact Allowed
Degree of Protection Against Water Ingress	Ordinary (IPXO)
Operating Input Voltage	120 VAC, Single Phase
Supply Current Frequency	50/60 HZ
Nominal Operating Voltage	120 VAC, Single Phase
Duty Cycle	20 minutes on , 20 minutes off
Information/ Regulatory	CLASS II Electrical System
Double Insulation	
Medical Equipment with respect to Electric Shock, Fire and Mechanical Hazards only, in accordance with UL60601-1/CAN/CSA C22.2 NO. 601.1	

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